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10/070,545	06/04/2002	Helge Myklebust	2810-17	4723

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,545	MYKLEBUST ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-13-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 15–26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of Group I, claims 1–14 and Group II, claims 15–26 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group I does not require an external defibrillator or decision limits. The subcombination has separate utility such as not requiring an analysis unit and to organize data continuously into segments or calculate combination parameters for each segment, but an external defibrillator for measuring ECG and CPR related parameters and providing therapy based on ECG or a CPR parameter.

Since Applicant has received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15–26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

2. The information disclosure statement filed March 7, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the lined through reference does not have a date. It has been placed in the application file, but the information referred to therein has

not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

3. The disclosure is objected to because of the following informalities: On page 10, the phrase "Spectral measures that are ..." (lines 16 –17) is unclear. It reads as an incomplete sentence.

On page 15, should the word "diverted" (line 16) be "derived?"

On page 3 of Applicant's **AMENDMENTS TO THE SPECIFICATION**, it appears that "EGG" (lines 12, and 17–18) should be "ECG" in the corresponding locations in the original specification.

On page 7 of Applicant's **AMENDMENTS TO THE SPECIFICATION**, it appears that "ROSG" and ROSX) (line 21) should be "ROSC" in the corresponding locations in the original specification.

Appropriate correction is required.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not disclose, "a table look in a m-dimensional table" (claim 4, lines 2–3).

Claim Objections

5. Claim 6 is objected to because of the following informalities: The claim limitation "the calculation unit" (lines 1–2) lacks antecedent basis in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1–14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter, which was not described in the original specification, is "organize CPR and ECG related data continuously into time segments" (claim 1, lines 11–12) in combination with the other elements in the claims. The original specification did not disclose organizing CPR and ECG related data continuously into time segments. Additionally, the subject matter, which was not described in the original specification, is "detect changes and magnitudes of combination parameters" (claim 1, lines 17–18) in combination with the other elements in the claims. The original specification did not disclose detecting changes and magnitudes of combination parameters. More subject matter, which was not described in the original specification, is "compare changes and magnitudes with corresponding data from empirical data" (claim 1, lines 19–20) in combination with the other elements in the claims. The

original specification did not disclose comparing changes and magnitudes with corresponding data from empirical data. This rejection is related to new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 1–14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the condition" in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitations "the number of defibrillation shocks" in line 3 and "the total number of defibrillation shock" in line 4. There is insufficient antecedent basis for these limitations in the claim. Also, the phrase "relative the total number of defibrillation shock" (line 4) is unclear. It is unclear what is being claimed. It appears that a word is missing after "relative" and that, in light of the former portion of the phrase, perhaps "shock" should be "shocks." Additionally, "the analysis unit (2)" (line 2) is vague because "(2)" is not used in claim 1. Furthermore, the word "where" (line 3) is vague. Is this supposed to be "wherein" or "whereby"?

Claim 4 recites the limitations "the value" in line 5 (appears twice), "the energy" in line 6, and "the input" in line 8. There is insufficient antecedent basis for these limitations in the claim. As stated in the Office Action mailed on 13 May 2005, "m different signal sequences" (lines 6–7) and "m different digital filters" (line 7) are inferentially included. It cannot be

determined if the m different signal sequences and m different digital filters are being positively recited or functionally recited.

Claim 5 recites the limitation "the value" in line 2. There is insufficient antecedent basis for this limitation in the claim. Again, as stated in the aforementioned Office Action, the phrases "derived from" (lines 3 and 5) make the claim incomplete. There is no element set forth for deriving. Therefore, it is unclear what element is performing this function.

As stated in the aforementioned Office Action, claim 6 recites the limitation "treatment parameters" in line 3. There is insufficient antecedent basis for these limitations in the claim. In addition, the phrases "algorithm for calculation" (line 6), and "information" (line 7) are inferentially included. Furthermore, the word "where" (line 6) is vague. Is this supposed to be "wherein" or "whereby"? Moreover, the phrase "is stored" (line 7) is not set forth to store information.

In claim 7, as stated in the aforementioned Office Action, the phrase "iterative search" (line 6) makes the claim incomplete because no element is set forth to iterate and it is unclear if this is a positive limitation. Furthermore, the phrases "information from a number of new patient treatments" (lines 3–4), "information from a number of earlier performed patient treatments" (lines 4–5) and "filter coefficients by m digital filters" (line 6) are inferentially included. Moreover, the phrases "adjusted iterative" (line 7), "performance of a classification" (line 8), "is adjusted iterative" (line 9), and "is defined" (lines 9–10) make the claim incomplete as there are no elements set forth for adjusting, performing, or defining and it is unclear if these are positive limitations. Furthermore, the word "where" (line 12) is vague. Is this supposed to be "wherein" or "whereby"? Claim 7 also recites the limitation "the m-dimensional matrix" in lines 27–28.

There is insufficient antecedent basis for this limitation in the claim. In summary, the entire claim is vague and indefinite. The claim does not set forth what elements are being positively recited or functionally recited. In addition, the claim does not set forth what elements are performing the functions listed in the claim.

As stated in the aforementioned Office Action in claim 8, "a receiver" (line 2) is inferentially included. Additionally, the phrase "shape of a display unit" (line 2) is vague. It is unclear what the limitation of "the shape" of a display unit is.

As stated in the aforementioned Office Action, claim 9 recites the limitation "the receiver" in line 1. There is insufficient antecedent basis for this limitation in the claim.

In claim 11, as stated in the aforementioned Office Action, "the analysis unit (2)" (line 2) is vague because "(2)" is not used in claim 1. Additionally, "to a receiver" (lines 5–6) is inferentially included. Claim 11 also recites the limitations "the numerical value" in line 4, "the positive change" in line 4, "the mean value" in line 5 and "the period" in line 5. There is insufficient antecedent basis for these limitations in the claim.

Claim 12 recites the limitations "the numerical value" in line 2, "the mean value" in line 3, and "the period" in lines 3–4. There is insufficient antecedent basis for these limitations in the claim. And, as stated in the aforementioned Office Action, "a display unit" (line 4) is inferentially included.

In claim 13, "an algorithm" (line 4) is inferentially included. And, as stated in the aforementioned Office Action, claim 13 recites the limitations "the numerical value" in line 2, "the positive change" in line 2, "the mean value" in line 3, "the period" in line 3 and "the choice of treatment" in line 4. There is insufficient antecedent basis for these limitations in the claim.

In claim 14, "wherein" (line 1) is vague. It should be "further comprising."

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1, 8–9, and 11–14 are rejected under 35 U.S.C. 102(e) as anticipated by Weil et al., U.S. Patent 5,957,856.

Weil discloses electrodes; a module; an analysis unit connected with a module (Fig. 7–8); an analysis unit is adapted to organize CPR and ECG related data continuously into time segments (Figs. 7–8); an analysis unit is adapted to calculate for each segment a combination characterizing a condition of the heart (column 6, lines 14–15; column 10, lines 1–4); an analysis unit is adapted to compare combination parameters and detect changes and magnitudes of combination parameters (Figs. 7–8; column 9, lines 24–28 and 57–60; column 10, lines 4–8); analysis unit with storage means and being adapted to compare changes and magnitudes with

corresponding data from empirical data representing earlier defibrillator treatments stored in storage means (Fig. 9, Abstract, lines 3–7); analysis unit being adapted to provide a decision support signal based on comparisons and CPR related data (Fig. 10). It is inherent that in order to monitor CPR data as Weil discloses, CPR sensors have to be present. Therefore, Weil inherently discloses sensors (Figs. 7–9). It is also inherent that in order to compare changes and magnitudes with corresponding data from empirical data representing earlier defibrillator treatments, a storage means has to be present. Therefore, Weil inherently discloses storage means (Figs. 9–10).

Weil discloses an output of an analysis unit is connected to a receiver in the shape of a display unit (Figs. 9–10); a receiver of a decision support signal is a defibrillator (column 5, line 19); an analysis unit identifies periods of positive change in a combination parameter together with parameters that characterize a treatment, and passes on a numerical value of a positive change, together with a mean value of each treatment parameter over a period, to a receiver (Figs. 7–10; column 10, lines 24–26); a receiver is a display unit (Fig. 10); a receiver is an algorithm for decision support for a choice of treatment (Figs. 7–9; column 8, lines 60–column 10, lines 1–26); a device for indicating patient specific information and/or specific information regarding a treatment is connected to an analysis unit (Fig. 9).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weil as applied to claim 1 above, and in view of Selker et al., U.S. Patent 5,724,983.

Weil does not disclose a calculation unit is connected to a data storage for storing, for each treatment parameters which describe a patient and parameters which describe a treatment, a calculation unit being connected to means for exchange of data, an exchange of data occurring on a regular basis towards a central computer, where a calculation unit receives optimized algorithm for calculation of a probability figure, and a computer receives information that is stored in a data storage. However, Selker discloses a calculation unit is connected to a data storage for storing (Figs. 1, and 3–5; column 3, lines 6–7), for each treatment parameters which describe a patient and parameters which describe a treatment (column 3, lines 61–62), a calculation unit being connected to means for exchange of data, an exchange of data occurring on a regular basis towards a central computer (Figs. 1, and 3–5), where a calculation unit receives optimized algorithm for calculation of a probability figure, and a computer receives information that is stored in a data storage (Figs. 1, and 3–5; column 9, lines 16–34 and 50–58) to notify medical support staff of the patient's condition (column 9, lines 35–36).

It would have been obvious to one of ordinary skill in the art at that time the invention was made to have modified the invention of Weil to include a calculation unit is connected to a data storage for storing, for each treatment parameters which describe a patient and parameters which describe a treatment, a calculation unit being connected to means for exchange of data, an exchange of data occurring on a regular basis towards a central computer, where a calculation unit receives optimized algorithm for calculation of a probability figure, and a computer receives information that is stored in a data storage, as taught by Selker to report the patient's condition.

15. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weil as applied to claim 1 above, and in view of Brown et al., U.S. Patent 5,683,424.

Weil does not disclose CPR related data includes compression and ventilation data retrieved form sensors. However, Brown discloses CPR related data includes compression and ventilation data retrieved form sensors (column 5, lines 16–19) to optimize CPR (column 5, lines 20–21).

It would have been obvious to one of ordinary skill in the art at that time the invention was made to have modified the invention of Weil to include CPR related data includes compression and ventilation data retrieved form sensors, as taught by Brown to administer optimal CPR.

Weil discloses combination parameters comprise a value of an m-dimensional vector derived from calculation of energy (column 3, lines 8–9) and frequency by a power density spectrum, where the power density spectrum is derived from an ECG signal segment (Figs. 4 and 6; column 4, line 17). Weil does not disclose a value of an m-dimensional vector derived from

calculation of frequency by the centre of gravity. However, Brown discloses combination parameters comprise a value of an m-dimensional vector derived from calculation of frequency by the centre of (Figs. 5–14; column 2, lines 40–41) to predict cardiac arrest outcomes (column 2, lines 47–48). Applicant's own admitted prior art discloses flatness (specification page 3, line 12).

It would have been obvious to one of ordinary skill in the art at that time the invention was made to have modified the invention of Weil to include a value of an m-dimensional vector derived from calculation of frequency by the centre of gravity, as taught by Brown to predict cardiac arrest outcomes.

Response to Arguments

16. Applicant's arguments with respect to claims 1–9 and 11–14 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

17. Examiner points out the IDS document that Applicant re-submitted is still non-compliant per the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 as stated in this and the Office Action mailed on 13 May 2005.

18. Regarding Applicant's amendments to claim 1 as argued on pages 19 and 21 of Applicant's **REMARKS/ARGUMENTS**, it is noted that the Applicant's specification does not disclose these limitations nor explain how these limitations would be enabled. The Applicant's disclosure is presented in like manner of all the prior art that the Examiner has searched regarding a system for evaluating the probability for the outcome of an immediately following defibrillator shock resulting in ROSC and providing a decision signal based thereon. The

specification does not disclose that both magnitude and rate of change are compared with earlier data nor does it disclose that both CPR and ECG signals are measured and used as claimed.

19. Additionally, Examiner has maintained some of the Specification objections and 35 U.S.C. 112 rejections made in the Office Action mailed on 13 May 2005 as Applicant did not address nor change the informalities or claims as noted in the rejections.

20. To make the record accurate, Examiner points out the following errors (and subsequent corrections) in the Office Action mailed on 13 May 2005: On page 4, "(all on line 19)" should read "(all on line 21)" (line 2); in numbered paragraph 3, "claims 1–14" should read "claims 2–14" (subparagraph 1, line 1). On page 6, ""m different filters"" (line 20) should read ""m different digital filters"". On pages 8 (last line, beginning with the phrase "In addition,) and 9 (lines 1–2), these should be a new paragraph that reads "In claim 14, "wherein" (line 1) is vague. It should be "further comprising." Likewise, "the analysis unit (2)" (line 3) is vague because "(2)" is not used in claim 1." On page 11, line 1, "element 112" should be eliminated.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to

37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
November 17, 2005
17 November 2005

GEORGE R. EVANISKO
PRIMARY EXAMINER
11/17/5